510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
DEVICE ONLY TEMPLATE

A. 510(k) Number:
K041358

B. Purpose for Submission:
New Device

C. Analyte:
N/A

D. Type of Test:
Blood Specimen Collection Device

E. Applicant:
Terumo Europe N.V.

F. Proprietary and Established Names:
Venoject® Luer Adapter

G. Regulatory Information:

1. Regulation section:
   21 CFR. 862.1675
2. Classification:
   Class II
3. Product Code:
   JKA
4. Panel:
   75

H. Intended Use:

1. Intended use(s):
   The Terumo® Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings that acts as the conduit between the collection needle and the collection container.

2. Indication(s) for use:
   The Terumo® Venoject Luer Adapter is a sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings. When blood samples are to be obtained with a single venipuncture, the luer adapter is a conduit between the collection needle and the collection container.

3. Special condition for use statement(s):
   N/A

4. Special instrument Requirements:
   N/A

I. Device Description:

The Terumo® Venoject Luer Adapter is a conduit between the collection needle and the collection container. The Terumo® Venoject Luer Adapter is a sterile, single use device consisting of a cannula joined to a screw connector which is connected to a male luer taper. The cannula is covered with a synthetic isoprene rubber tip for stopping blood flow. When blood is collected using an evacuated blood collecting system, the collection container is placed over the cannula, pushing the rubber tip back, allowing blood flow. When the collection container is removed, the rubber tip extends back over the cannula, stopping blood flow. The luer adapter has no direct patient contact.

J. Substantial Equivalence Information:

1. Predicate device name(s):
   The Terumo® Venoject Luer Adapter manufactured by the Terumo Corporation.

2. Predicate K number(s):
   K983490

3. Comparison with predicate:

Similarities		
Item	**Device**	**Predicate**
Intended Use	Sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings.	Sterile, non-invasive device that permits blood specimen collection from hypodermic needles, blood vessel catheters, or blood collection systems/devices with luer fittings.
Materials	Stainless Steel Cannula Silicone Oil Lubricant Epoxy glue adhesive Synthetic Isoprene Rubber Tip Polypropylene Needle Polypropylene and polyethylene Connector Cap	Stainless Steel Cannula Silicone Oil Lubricant Epoxy glue adhesive Synthetic Isoprene Rubber Tip Polypropylene Needle Polypropylene and polyethylene Connector Cap
Principle of Operation	Manual	Manual
Expiration	30 months	30 months

Differences		
Item	**Device**	**Predicate**
Sterilization	Ethylene Oxide Gas to SAL 10^{-6}	Gamma Radiation to SAL 10^{-6}

K. Standard/Guidance Document Referenced (if applicable):

European Pharmacopoeia (2002) 2.6.8 (4th edition)
EN 180 30993-4:1992-DAM 1"Biological testing of medical devices- Part 4:Tests for interaction with blood.

L. Test Principle:

N/A

M. Performance Characteristics (if/when applicable):

1. Analytical performance:
    a. *Precision/Reproducibility:*
    N/A
    b. *Linearity/assay reportable range:*
    N/A
    c. *Traceability (controls, calibrators, or method):*
    N/A
    d. *Detection limit:*
    N/A
    e. *Analytical specificity:*
    N/A
    f. *Assay cut-off:*
    N/A

2. Comparison studies:
    a. *Method comparison with predicate device:*
    The Terumo® Venoject Luer Adapter manufactured by Europe N.V that was sterilized by Ethylene Oxide gas was compared against the Terumo® Venoject Luer Adapter manufactured by Terumo Corporation that was sterilized by gamma radiation. The current device at ages 0, 1 and 2.5 years was compared against the predicate in the following tests:
    1) bonding strength between hub and cannula, 2) penetration force at setting side, 3) bonding strength between the hub and rubber tip, 4) resistance torque to screw and unscrew the luer adapter on and off the holder, 5) resealability of rubber tip, 6) conical fitting, 7) air and liquid leakage and 8) push back force.
    The results of the tests performed showed that sterilization methods did not affect the safety and effectiveness of the Terumo® Venoject Luer Adapter manufactured by Europe N.V.

    b. *Matrix comparison:*
    N/A

3. Clinical studies:
    a. *Clinical sensitivity:*
    N/A
    b. *Clinical specificity:*
    N/A
    c. *Other clinical supportive data (when a and b are not applicable):*
    N/A

4. Clinical cut-off:
    N/A

5. Expected values/Reference range:
    N/A

N. Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.